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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,625	06/27/2003	Shelby L. Cook	022956-0214	9377

21125 7590 09/20/2007
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EXAMINER

NGUYEN, TUAN VAN

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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09/20/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Sp

Office Action Summary	Application No. 10/615,625	Applicant(s) COOK ET AL.	
	Examiner Tuan V. Nguyen	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after the final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 29, 2007 has been entered.

Response to Amendment

2. Applicant's arguments with respect to Donnelley reference that does not disclose a suture channel formed in an elongated body wherein the suture channel is oriented substantially transverse to a longitudinal axis of symmetry of the body and that the suture channel of Donnelley is oriented obliquely angled to a longitudinal axis of symmetry L of the body, have been fully considered but not persuasive. Examiner respectfully traverses the applicant's remarks: Since the definition of the word "transverse" according to the Merriam-Webster's Collegiate Dictionary, Tenth Edition principal copyright 1993, page 1256, is **1: acting, lying, or being across : set crosswise or 2: made at right angles to the long axis of the body.** Since applicant fails to further define the suture channel made at right or perpendicular with the longitudinal axis. Therefore, examiner asserts that the suture channel 24

as shown in Figures 1A and 1B of Donnelley reference is being cross with the longitudinal axis of symmetry (axis L shown in Figure 1A), therefore, it read on the "substantially transverse" limitation as claimed by applicant.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1, 4-13, 15-16 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Pedlick et al. (U.S. 6,270,518).**
5. Referring to claims **1, 4-13, 15-16 and 23**, Pedlick discloses (see Figs. 35-36 and 38-41) a bioabsorbable suture anchor 301 for anchoring tissue to a bone, comprising: an elongate body 310 defined by a longitudinal axis; a first, leading end 302, includes a rounded distal end 304, and a second, trailing end 306; the elongate body comprising two opposed surfaces 320 between the first and second ends, and a plurality of sidewalls 312, 316 extending between the two opposed surfaces; a flared portion 308, includes biting edge 322 formed on the second end and extending from one of the sidewalls, the flared portion being adapted to

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engage and anchor into bone tissue; and a suture channel 330, that includes rounded edge 330 on both sides, formed in the elongate body for passage of a suture strand therethrough, the suture channel extending between the two opposed surfaces, and strand of suture is inserted through the channel, and the center of the channel is offset from the longitudinal axis of the anchor (see Fig. 41); wherein the suture anchor is capable for user to toggle and anchor inside a bone cavity by the suture; and the anchor also includes a blind hole 334 for engaging with insertion tool (see Fig. 36), wherein the insertion tool having elongate member with a proximal, handle end and a distal, attachment end (see col. 14, lines 1–60). Pedlick also discloses the method of deployment the anchor into a bone hole as claimed in claims 19-20 (see col. 18, line 53 to col. 19, line 55).

6. **Claims 1, 3-13, 15-16, 18 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Donnelly et al. (U.S. 6,773,436).**
7. Referring to claims 1, 3-13, 15-16, and 18, Donnelly discloses (see Figs. 1-2C, 4a-4b and 9A-9D) a bioabsorbable suture anchor 10 for anchoring tissue to a bone, comprising: an elongate body 12 defined by a longitudinal axis L; a first, leading end 14, includes a rounded distal end, and a second, trailing end 16; the width of the second trailing end is 3 mm at its widest portion (see col. 8, lines 19-21); the elongate body comprising two opposed surfaces 12 between the first and second ends, and a plurality of sidewalls 20, extending between the two opposed surfaces; a flared portion, includes biting edge 22 formed on the second end and extending from one of the sidewalls, the flared portion being adapted to engage

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and anchor into bone tissue; and a suture channel 24, that includes rounded edge 28 on both sides, formed in the elongate body for passage of a suture strand 2 (see Fig. 2a) therethrough, the suture channel extending between the two opposed surfaces, and strand of suture is inserted through the channel, and the center of the channel is offset from the longitudinal axis of the anchor (see Fig. 4a and 4b); wherein the suture anchor is configured to toggle and anchor inside a bone cavity by the pulling on the suture (see col. 8, lines 50-53); and the anchor also includes a blind hole 30 for engaging with insertion tool 400 (see Fig. 9), Figure 9 shown the insertion tool having elongate member the elongate member can be use as a handle, and a distal, attachment end (see col. 3, line 43 to col. 4, line 65). Referring to **claim 19**, Donnelly also discloses the method of deployment the anchor into a bone hole as claimed by the applicant (see col. 8, lines 17-65 and claims 19-20).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
10. **Claims 2, 3, 14, 17, and 18 are rejected under 35 U.S.C. 103(a) as unpatentable over Pedlick et al. in view of Pedlick et al.**
11. Referring to **claims 2, 3, 17, and 18**, Pedlick discloses the size of suture anchor is 3 mm (see col. 9, line 24). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to design a suture anchor having elongate body is in the range of about 2-6 mm and the width is in the range of about 1-3 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.
12. Referring to **claim 14**, Pedlick discloses the suture anchor may be made of bioabsorbable or non-bioabsorbable polymer (see col. 10, lines 45-60). It is old and well known in the art that polymer, Nitinol, stainless steel has its own natural color. The natural color of the material that made the suture anchor can be used as visual indication by the naked eyes of the surgeons during the surgery or by X-ray after the surgery (if the material is stainless steel) for the indication of the location of the anchor in the surgical site. It is old and well known that color such

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as yellow, red, and blue enhancing the ability of visual recognition to the human eye. Therefore, it would have been obvious matter of design choice to one of ordinary skill in the art to use blue dye to replace the nature color of the stainless steel and polymer because the blue color would enhancing the visual recognition to the surgeon as compare to the nature color of stainless steel and polymer.

Further, Applicant has not disclosed that the blue dye provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the color of Pedlick device, and applicant's invention, to perform equally well.

13. **Claims 2, 3, 14, 15, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donnelly et al. in view of Donnelly et al.**
14. Referring to **claims 2, 3, 17, and 18**, Donnelly discloses the diameter size of suture anchor is 3 mm and the suture anchor having an overall size smaller than conventional bone anchors (see col. 4, lines 35-43). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to design a suture anchor having elongate body is in the range of about 2-6 mm and the width of the anchor is about 1 mm to about 3 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.
15. Referring to **claim 14**, Donnelly discloses the suture anchor may be made of bioabsorbable or non-bioabsorbable polymer (see col. 4, lines 62-68 and col. 6,

lines 26-32). It is old and well known in the art that polymer and Titanium has its own natural color. The natural color of the material that made the suture anchor can be used as visual indication by the naked eyes of the surgeons during the surgery or by X-ray after the surgery (if the material is Titanium) for the indication of the location of the anchor in the surgical site. It is old and well known that color such as yellow, red, and blue enhancing the ability of visual recognition to the human eye. Therefore, it would have been obvious matter of design choice to one of ordinary skill in the art to use blue dye to replace the nature color of the stainless steel and polymer because the blue color would enhancing the visual recognition to the surgeon as compare to the nature color of stainless steel and polymer. Further, Applicant has not disclosed that the blue dye provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the color of Pedlick device, and applicant's invention, to perform equally well.

16. Referring to **claim 15**, Donnelly discloses the invention substantially as claim except for the insertion tool 400 having a handle. Figure 9 of Donnelly reference shown the insertion tool having an elongate member, wherein the elongate member can be use as a handle. In any event, here it is noted that the insertion tool for deployment of a suture anchor having a handle that attached to the proximal end of the elongate member is old and well known in the art.

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17. **Claims 2, 3, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pedlick et al. in view of Cassidy (U.S. 6,280,474).**
18. Referring to claims **2, 3, 17, and 18**, Pedlick discloses the invention substantially as claimed except for a specific range of the length of the anchor from about 2 mm to about 6 mm and the width at the widest point of the anchor is about 1 mm to about 3 mm. However, Cassidy discloses a bone anchor can be used to attached small bone to small bone or soft tissue to bone (see Figures 11B and 6B and col. 3, lines 29-38) wherein the overall dimensions of the anchor is 1 mm to about 6 mm wide and between 3 mm to 30 mm long (see col. 3, lines 62-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to design a suture anchor having elongate body is in the range of about 2-6 mm and the width of the anchor is about 1 mm to about 3 mm for a specific bone in the body, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.
19. **Claims 2, 3, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donnelly et al. in view of Cassidy (U.S. 6,280,474).**
20. Referring to claims **2, 3, 17, and 18**, Donnelly discloses the invention substantially as claimed except for a specific range of the length of the anchor from about 2 mm to about 6 mm and the width at the widest point of the anchor is about 1 mm

to about 3 mm. Here it is noted that Donnelly discloses the dimension of the width at the widest point of the anchor is 3 mm and the overall dimension of the anchor is smaller than conventional bone anchors (see col. 4, lines 35-43). However, Cassidy discloses a bone anchor can be used to attached small bone to small bone or soft tissue to bone (see Figures 11B and 6B and col. 3, lines 29-38) wherein the overall dimensions of the anchor is 1 mm to about 6 mm wide and between 3 mm to 30 mm long (see col. 3, lines 62-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to design a suture anchor having elongate body is in the range of about 2-6 mm and the width of the anchor is about 1 mm to about 3 mm for a specific bone in the body, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

21. **Claims 21-25 are rejected under 35 U.S.C. 103(a) as unpatentable over Donnelly et al. (US 6,773,436) in view of Pedlick.**
22. The device of Donnelly discloses (see paragraph 7 above) the invention substantially as claimed except for suture channel is substantially perpendicular with the longitudinal axis of the body. However, Pedlick discloses and suture anchor comprising, among other things, a suture channel that perpendicular with the longitudinal axis of the body. Therefore, it would have been obvious to one of ordinary skill in the art to modify the suture channel of Donnelly device with the

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suture channel as disclosed by Pedlick for the purpose of simplify the manufacturing of the anchor because the oblique angled channel with the longitudinal axis of the body is more difficult to create than a channel that perpendicular with the longitudinal axis of the body. Further, applicant has not disclosed that the suture channel substantially transverse with the longitudinal axis of the body provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the suture channel of Donnelly device, Pedlick device, and applicant's invention, to perform equally well.

23. Claim 19 is rejected under 35 U.S.C. 103(a) as unpatentable over Pedlick et al. in view Donnelly et al. (US 6,773,436).

24. The device of Pedlick discloses (see paragraph 6 above) the invention substantially as claimed except for the step of toggling the suture anchor. However, Donnelley discloses such a step (see col. 8, lines 50-53). Therefore, it would have been obvious to one of ordinary skill in the art to use the suture anchor of Pedlick to replace the anchor of Donnelly for the purpose of simplify the manufacturing of the anchor because the oblique angled channel with the longitudinal axis of the body is more difficult to create than a channel that perpendicular with the longitudinal axis of the body and to further provide the surgeon the ability of toggling the anchor thereby locking the anchor into the bone.

Double Patenting

25. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

26. Claim 19 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,232,455 to

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Pedlick et al. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen
September 10, 2007


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
9/12/07.